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(54) Title: FOAMABLE FORMULATION AND FOAM (57) Abstract There is described a foamable formulation comprising a foamable carrier and an active ingredient which may be admixed with the carrier or packaged separately and dispersed into the carrier during the foaming process. Alginate gel is a preferred foamable carrier. The foam produced from such a formulation, and a foam sheet produced by drying the foam, also form part of the invention. The formulation, foam and foam sheet are especially useful for medical applications, for example in treating burns. An apparatus to store the components of the formulation and to generate the foam is also described.		

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1 **"Foamable Formulation and Foam"**

2

3 The present invention is concerned with a foamable
4 formulation and the foam formed therefrom.

5

6 A wide variety of gels, creams, ointments, lotions etc
7 are available for application to a body surface. The
8 exact content of such compositions generally depends
9 upon the purpose of application which may be, for
10 example, to clean a body surface, to promote healing of
11 any wound or injury, to prevent an exposed area of the
12 body from drying out, to prevent infection etc. In
13 certain circumstances the composition may include an
14 active ingredient which is administered to the patient
15 by application of the composition.

16

17 One example of a commercially available gel in
18 INTRASITE™ produced by Smith & Nephew Ltd. This
19 hydrogel contains hydrated carboxymethylcellulose as
20 its main ingredient, and is applied to wounds in gel
21 form as a primary treatment in order to clean the
22 exposed surface by aiding removal of cell debris, dirt
23 etc. In addition to acting as a sloughing agent, the
24 gel also keeps the wound from drying out, thereby
25 promoting healing.

1 Another example of a gel suitable for use on a wound
2 dressing is described in EP-A-0586260 of Courtaulds
3 Fibres Ltd. The gel disclosed is an alginate gel
4 having an alginate content of 2 to 11 percent by
5 weight.

6
7 Viewed from one aspect, the present invention provides
8 a formulation for application to a body surface as a
9 foam, said formulation comprising an active ingredient
10 and a foamable, preferably physiologically acceptable,
11 carrier. The active ingredient(s) may be present as an
12 integral part of the formulation, or may be held
13 separately to other ingredients of the formulation,
14 being combined therewith during formation of the foam.
15 Optionally, the formulation may also comprise a foaming
16 agent (for example a surfactant) which is capable of
17 promoting production of a foam structure.

18
19 In one embodiment, the present invention provides a,
20 physiologically acceptable (preferably pharmaceutically
21 acceptable), foamable carrier and an active ingredient
22 packaged separately thereto which is admixed with the
23 foamable carrier during the foaming process.

24
25 The term "active ingredient" is used herein to refer to
26 any agent which affects the metabolism or any metabolic
27 or cellular process of the patient (including growth
28 factors nutrients and living cells), promotes cleaning
29 of the area to which it is applied (for example aids
30 removal of a debris, dirt, bacteria, malodours and the
31 like), combats infection, hypergranulation,
32 inflammation and/or aids healing.

33
34 The term "foamable carrier" refers to any ingredient
35 which is compatible with the active ingredient and
36 which is capable of forming a foam. Conveniently the

1 foamable carrier does not affect the function of the
2 active ingredient in a detrimental manner. Desirably
3 the foamable carrier is non-irritant when maintained in
4 contact with a body surface for several hours. The
5 foamable carrier may be a gel, for example an alginate
6 gel.

7
8 The foam produced may be maintained on the body area,
9 to form a protective covering, for example over a
10 wound. Additionally, the foam may deliver the active
11 ingredient, preferably in a controlled release manner.
12 In one embodiment the foam acts as a transdermal
13 delivery system. The foam may be exposed to the
14 atmosphere so that it dries into a coating, or may be
15 covered by conventional dressings.

16
17 As an example, the foam may be used to treat
18 dermatological conditions (including psoriasis, atopic
19 and allergic eczema). It may be convenient in this
20 embodiment for the foam to deliver an active ingredient
21 normally used to alleviate such conditions, for example
22 a steroid such as hydrocortisone.

23
24 In another embodiment the foam may be used to treat
25 burns or scalds, including sunburn.

26
27 In another embodiment the foam may be applied
28 cosmetically, and for example may include skin
29 moisturising agents, nutritional agents and growth
30 factors suitable to promote skin regeneration. A foam
31 intended for cosmetic use may include colorants or
32 pigments so that the foam may be applied to the skin as
33 a cosmetic or to disguise any blemishes in the skin.

34
35 The foam may be used prophylactically. In particular a
36 foam containing a UV blocking agent may be applied to

1 exposed areas of the skin to protect it from the
2 effects of the sun.

3
4 The formulation of the invention is applied to the body
5 site of interest in the form of a foam and it is
6 therefore essential that the composition undergoes a
7 foaming process before application to the body. In the
8 foaming process gas is forced into or is formed within
9 the formulation to entrap small bubbles of gas therein,
10 thereby forming the foam. Any suitably gas or gas
11 producing system can be used to produce the foam.
12 Mention may be made of butane and nitrous oxide, but
13 other gases are also suitable. Conveniently the foam
14 may be produced by conventional means such as by using
15 aerosol technology.

16
17 The formulation according to the present invention may
18 be stored in any convenient container until required.
19 Generally, the container will be designed to preserve
20 the sterile nature of the formulation. Conveniently
21 the container will be provided with means to foam the
22 composition when required.

23
24 Thus the present invention also provides an apparatus
25 which produces a physiologically acceptable foam as
26 described above. Generally, the foam will be produced
27 from sterile ingredients.

28
29 Viewed from another aspect, the present invention
30 provides a closed container, containing therein a
31 formulation as described above, said container being
32 capable of expelling said formulation in the form of a
33 foam. For example, the container may be an aerosol
34 canister, containing a pressurized gas which in use
35 causes production of the foam. Alternatively, the gas
36 may be produced by a chemical reaction when two

1 different ingredients (for example contained in two
2 portions of a sachet) are admixed together. In one
3 embodiment the closed container has separate reservoirs
4 for the foamable carrier and the active ingredient.
5 Thus, the foamable carrier and the active ingredient
6 are stored separately during storage and are admixed
7 together in suitable proportions during the foaming
8 process.

9
10 The present invention thus provides an apparatus to
11 produce a foam for application to a body surface, from
12 a formulation as defined above, said apparatus
13 comprising:

14
15 a. a closed container having

16
17 i) a reservoir containing said foamable carrier;

18
19 ii) a reservoir containing said active
20 ingredient; and

21
22 b. foaming means to produce a foam from said foamable
23 carrier.

24
25 Optionally a foaming agent may be mixed with the
26 foamable carrier.

27
28 Prior to the foaming process, the foamable carrier is
29 preferably in the form of a gel. The gel may be
30 sterilised and this is generally desirable where the
31 foam is intended for medical use. Usually,
32 sterilisation will take place by autoclaving the
33 formulation, since this is currently the most economic
34 means of achieving sterilisation. Autoclaving at
35 temperatures of from 100°C to 125°C for under $\frac{1}{2}$ hour is
36 normally sufficient. Generally, the autoclaving

1 process should be as mild as possible, whilst being
2 sufficient to sterilise the formulation. For example,
3 autoclaving at temperatures of about 121°C for 15-20
4 minutes is acceptable. The autoclaved formulation may
5 then be foamed when cool. It is also possible,
6 however, to sterilise the formulation by other means,
7 for example by γ -irradiation or e-beam irradiation. It
8 has been found that autoclaving the gel may cause the
9 MW of the foamable carrier to be slightly reduced.
10 Consequently it may be desirable to select a foamable
11 carrier having a higher MW than that ultimately
12 required.

13
14 The foam forms an air-tight cover around any wound or
15 injury to which it is applied, and this prevents that
16 area from drying out and may also combat infection.
17 The-advantages of applying a topical product in the
18 form of a foam include:

- 19
20 1. Easy rapid application,
21 2. Conforms to surface irregularities,
22 3. Insulates the wound,
23 4. Cools the tissues,
24 5. Offers antibacterial action to prevent
25 infection,
26 6. Biocompatibility with tissue,
27 7. Suitable for use as a vehicle for the
28 administration of pharmaceutical agents,
29 and/or
30 8. Maintains a moist environment.

31
32 It has been observed that the foam produced from the
33 formulation of the present invention may subside over a
34 period of time (for example 3 to 24 hours, especially 6
35 to 12 hours) as some of the gas entrapped in the foam
36 structure escapes. The foamed formulation gradually

1 dries to produce a foam (i.e. closed cell) sheet which
2 still retains a basic foam structure and which may
3 cover the site to which the foam was applied. This
4 foam sheet can be left in place as a protective cover
5 over a wound, may be used to deliver an active
6 ingredient to the site, etc. It is possible to produce
7 the sheet separately as a dressing for a wound or
8 injury for direct application in that form. The foam
9 sheet is therefore a yet further aspect of the present
10 invention.

11
12 Generally, the formulation of the present invention
13 will be applied directly to the body site of interest
14 in the form of a foam, the foam being produced from any
15 suitable device (such as an aerosol) immediately before
16 application. It is, however, possible for a quantity
17 of the foamed formulation to be produced and then
18 applied onto the body site by any suitable means, for
19 example by hand or by spatula. This method may be
20 required for wounds having a narrow opening.

21
22 As stated above, the foam may also be produced on a
23 suitable surface and then dried to produce the foam
24 sheet described above. Generally, the production of
25 the sheet will take place under sterile conditions.
26 The sheet may be divided into a convenient size and may
27 be packaged. Optionally the foam sheet may be produced
28 on contoured surface so that it is moulded to a pre-
29 determined shape.

30
31 It has further been observed that where the foam is
32 covered with an airtight cover (for example a plastics
33 backing) the foam structure is maintained, without
34 collapsing to a foam sheet. Covering the freshly
35 produced foam with a plastics cover (for example a
36 plastics film or a plastics bag) may be desirable in

1 circumstances where the bulk of the foam is to be
2 retained.

3
4 Examples of suitable foamable carriers for use in the
5 composition of the present invention include (but are
6 not limited to) alginate and derivatives thereof,
7 carboxymethylcellulose and derivatives thereof,
8 collagen, polysaccharides (including, for example,
9 dextran, dextran derivatives, pectin, starch, modified
10 starches such as starches having additional carboxyl
11 and/or carboxamide groups and/or having hydrophillic
12 side-chains, cellulose and derivatives thereof), agar
13 and derivatives thereof (such as agar stabilised with
14 polyacrylamide), polyethylene oxides, glycol
15 methacrylates, gelatin, gums such as xanthum, guar,
16 karaya, gellan, arabic, tragacanth and locust bean gum.
17 Also suitable are the salts of the aforementioned
18 carriers, for example, sodium alginate. Mixtures of
19 any of the aforementioned carriers may also be used, as
20 required.

21
22 Preferred foamable carriers include alginate,
23 carboxymethylcellulose, the derivatives and salts
24 thereof and mixtures of any of these. Alginate (the
25 derivatives or salts thereof, such as sodium and
26 calcium alginate) are especially preferred. Foamable
27 carriers having a molecular weight of from 10,000 to
28 200,000 kDa are preferred, especially over 100,000 kDa,
29 for example 150,000 to 200,000 kDa, may be used.

30
31 The formulation may further comprise a foaming agent,
32 which promotes the formation of the foam. Any agent
33 having a surfactant character may be used. The
34 surfactants may be cationic, non-ionic or anionic.
35 Examples of suitable foaming agents include cetrimide,
36 lecithin, soaps, silicones and the like. Commercially

1 available surfactants such as Tween™ are also suitable.
2 Cetrimide (which additionally has an anti-bacterial
3 activity) is especially preferred.

4

5 The formulation of the present invention (and thus the
6 foam) may be used to deliver pharmaceutically active
7 agents, in particular to deliver such agents in a
8 controlled release manner. Mention may be made of:

9

10 Antiseptics, Antibacterials and Antifungal agents,
11 such as Chlorhexidine, acetic acid, polynoxylin,
12 povidone iodine, mercurochrome phenoxyethanol,
13 acridene, silver nitrate, dyes eg brilliant green,
14 undecanoic acid, silver sulphadiazine, silver
15 proteins and other silver compounds,
16 metronidazole, benzaclonium chloride;

17

18 Nutritional agents, such as vitamins and proteins;

19

20 Growth factors and healing agents, including
21 Ketanserine a serotonomic blocking agent;

22

23 Living Cells;

24

25 Enzymes include streptokinase and streptodormase;

26

27 Elements - zinc, selenium, cerium, copper,
28 manganese, cobalt, boron, arsenic, chromium
29 silver, gold, gallium;

30

31 Charcoal;

32

33 Desloughing and Debriding agents such as
34 hypochlorite and hydrogen peroxide;

35

36 Astringents including potassium permanganate;

1 Antibiotics exemplified by neomycin and framycetin
2 sulphate, sulfamylon, fusidic acid, mupirocin,
3 bacitracin, gramicidin.

4
5 A particularly convenient way of presenting metal ions
6 (for example silver or calcium ions) is via a glass
7 composition. The glass may be ground into particle
8 form and then incorporated into the formulation of the
9 present invention. Optionally the glass is capable of
10 sustained or delayed release of the metal ions.

11 Reference may be made to WO-A-90/08470 of Giltech Ltd
12 which describes a suitable glass composition for
13 delivering silver ions. Thus, a preferred embodiment
14 of the invention is a formulation as described above
15 wherein particles of a metal ion (preferably silver
16 and/or calcium ion) releasing glass are admixed into
17 the formulation during the foaming process.

18
19 Other preferred pharmaceutically active agents include
20 Chlorhexidine, povidone iodine and cetrimide.

21
22 In addition the formulation of the present invention
23 may further comprise other conventional additives such
24 as plasticisers and humectants (such as glycerol,
25 propane-1,2-diol, polypropylene glycol and other
26 polyhydric alcohols), free radical scavengers to
27 stabilise against the effects of sterilisation by
28 irradiation, viscosity-adjusting agents, dyes and
29 colorants, and the like.

30
31 Particularly preferred formulations of the present
32 invention include:

- 33
34 1. Alginate/cetrimide
35 - alone or with chlorhexidine or povidone iodine
36 or other agents.

Uses

- a. Hand and body washing (including scalp shampoo);
- b. Topical agents for skin carriage sites and wounds.

2. Alginate/cetrimide/calcium and silver ion releasing glass (eg Arglaes™)
- alone or with other agents

The calcium released from the glass will stabilise the alginate by forming the insoluble calcium salt.

Uses

- a. Silver is effective against gram negative species eg Proteus, E Coli, Pseudomonas & Klebsiella aerobacters;
- b. Cetrimide is a broad spectrum antibacterial and antifungal agent, most effective against gram positive species eg Staphylococcus epidermidis and aureus (wounds are generally infected on a 50:50 basis with gram positive or negative species); and
- c. sloughy wounds, granulating or epithelialising wounds, black necrotic tissue, clinically infected wounds, malodorous wounds and burns and scalds and as a haemostat.

3. Hydrogel foams in general

eg Carboxymethylcellulose

eg Gelatin - preformed foam could provide an

1 improved presentation for burn coverings,
2 temporary soft tissue implants, etc.

3

4 4. Mixtures

5 eg Alginate/collagen mixtures.

6

7 Alginates are particularly preferred as the foamable
8 carrier in the formulation of the present invention.
9 Alginates are especially useful for application to
10 wounds since the alginate promotes the healing process
11 and is itself slowly absorbed and metabolised in the
12 body. Sodium alginate is soluble whereas calcium
13 alginate is insoluble. In the present invention
14 therefore it is desirable for a careful mixture of
15 sodium and calcium alginate to be produced, the exact
16 ratio being altered in accordance with the desired
17 characteristics of the foam. An alginate-based foam
18 may therefore be easily removed simply by washing away
19 in saline. Commercially available alginates suitable
20 for use in the present invention include Manucol DMF,
21 Manucol LKX, and Keltone™ for example Keltone HV™ which
22 is a finely ground fibrous sodium alginate suitable for
23 use in food preparations. High molecular weight
24 alginates are preferred, for example these having a
25 molecular weight of 50,000 kDa or above, for example
26 100,000 to 200,000 kDa.

27

28 The present invention further provides the use of a
29 formulation for production of a foam suitable for
30 medical or veterinary purposes, especially for the
31 controlled released delivery of the active ingredient.

32

33 For example, the present invention provides the use of
34 a formulation to produce a foam suitable for
35 application to wounds or injuries, especially burns.
36 The invention further provides the use of a formulation

1 to produce a foam which delivers an active ingredient,
2 such as a cleaning agent or a medicament to the body.
3 For example, the foam produced may be used as a soap
4 alternative for doctors or other medical staff to clean
5 their hands before seeing a patient. Use of the foam
6 could eliminate the need for washing in water.

7
8 Additionally, the present invention provides the use of
9 the foam itself for application (in particular topical
10 application) to a body. Therefore the foam may be used
11 to deliver a drug or any other medicament, may be used
12 as a sloughing agent to clean a wound etc, or may be
13 used to provide a sterile covering for a wound etc.

14
15 The present invention also provides the use,
16 separately, of the container, of the composition and of
17 the foam described above to produce a wound dressing in
18 the form of a foam sheet.

19
20 In a further aspect, the present invention provides a
21 method of treatment of the human or animal (preferably
22 mammalian) body, said method comprising administering
23 to said body a foam or a foam sheet as hereinbefore
24 defined. Optionally the foam and/or foam sheet may
25 deliver a drug or a medicament to the body.

26
27 The foam and the foam sheet of the present invention
28 are especially suitable for treatment of burns.

29
30 The present invention will now be described with
31 reference to the following examples:

32
33 Unless otherwise stated, the percentage amounts of
34 ingredients are given on a percentage by weight basis.

35
36

1 Example 1

2

3 A composition according to the present invention was
4 formed by admixing the following ingredients together:

5

6 3% Manucol LKX

7 1% Cetrimide

8 80:20 di-ionised water : propan-1,2-diol

9 3% Arglaes (a silver ion releasing glass)

10

11 A gel composition was formed and autoclaved at
12 approximately 121°C for 15 to 20 minutes. The gel
13 produced was firm but mobile.

14

15 The gel was foamed using an aerosol canister and a fine
16 celled, highly conformable, thick, creamy foam was
17 produced. There was little slump, little flow, fairly
18 stable, did not go back to a gel when rubbed. The foam
19 was cool and soothing. Once left to dry the flat foam
20 left is still moist, cool sponge. The silver presence
21 was showing.

22

23 Example 2

24

25 A composition according to the present invention was
26 formed by admixing the following ingredients together:

27

28 3% Manucol DMF

29 1% Cetrimide

30 80:20 di-ionised water : propan-1,2-diol

31

32 A gel composition was formed and autoclaved at
33 approximately 121°C for 15 to 20 minutes. The gel
34 produced was firm but mobile.

35

36 The gel was foamed using an aerosol canister and a fine

1 celled, highly conformable, thick foam was produced.
2 There was no slump or flow. The foam was very stable
3 and did not go back to a gel when rubbed. It was cool
4 and soothing. Once left to dry the flat foam left was
5 still moist, fragile and sponge-like.

6

7 Example 3

8

9 A composition according to the present invention was
10 formed by admixing the following ingredients together:

11

12 3% Keltone

13 1% Cetrimide

14 80:20 di-ionised water : glycerol

15

16 A gel composition was formed and autoclaved at
17 approximately 121°C for 15 to 20 minutes. The gel
18 produced was firm but mobile.

19

20 The gel was foamed using an aerosol canister and a fine
21 celled, thick foam was produced. There was no slump or
22 flow. The foam was very stable, had a dry feeling,
23 plasticity, and did not go back to a gel when rubbed.
24 It was cool and soothing. Once left to dry the flat
25 foam was still moist, fragile and sponge-like.

26

27 Example 4

28

29 A composition according to the present invention was
30 formed by admixing the following ingredients together:

31

32 350mls di-ionised water

33 2gms Cetrimide

34 20gms Carboxymethylcellulose

35 40mls Glycerin

36

1 A gel composition was formed. The gel produced was
2 very sticky.

3

4 The gel was foamed using an aerosol canister and a
5 thixotropic, minimum flow, fine cellular foam was
6 formed. It had a thick texture that was virtually
7 unchanged when left overnight.

8

9 Example 5

10

11 A composition according to the present invention was
12 formed by admixing the following ingredients together:

13

14 80mls di-ionised water
15 2gms Cetrimide
16 20mls Glycerin
17 4gms Carrageenan

18

19 A gel composition was formed. The gel produced was
20 thick and foamed slightly when cetrimide was added
21 (acts like an alginate).

22

23 The gel was foamed using an aerosol canister and a
24 thixotropic, minimum flow, fine cellular foam was
25 formed. It did not collapse to touch and was difficult
26 to break down into a gel again. After being left
27 overnight it was sticky and non-cohesive.

28

29 Example 6

30

31 A composition according to the present invention was
32 formed by admixing the following ingredients together:

33

34 60mls di-ionised water
35 1.2gms Cetrimide
36 4mls Gelatin

1 A gel composition was formed. The gel produced was
2 firm and rigid. Just before foaming 60 mls boiling di-
3 ionised water was added and a warm liquid was formed.
4 When pressurised the temperature dropped.

5
6 After the liquid reached the correct temperature within
7 the foaming canister a thick fully expanding foam was
8 produced. It was fine celled and did not break down
9 easily. Initially it was non-thixotropic and then
10 developed into a stable foam. Overnight a firm closed
11 cell sponge with very good handling strength was
12 produced.

13
14 Example 7

15
16 A composition according to the present invention was
17 formed by admixing the following ingredients together:

18
19 80mls di-ionised water
20 1ml Tween 80
21 3gms Keltone
22 20mls glycerin

23
24 A gel composition was formed. The gel produced was
25 firm but mobile.

26
27 The gel was foamed using an aerosol canister and a fine
28 celled, thick, thixotropic foam was produced that
29 stabilised very quickly.

30
31 Example 8

32
33 A composition according to the present invention was
34 formed by admixing the following ingredients together:

35
36 3% Keltone

1 1% Cetrimide
2 80:20 di-ionised water : glycerol
3 4% povidone iodine
4

5 A gel composition was formed and autoclaved at
6 approximately 121°C for 15 to 20 minutes. The gel
7 produced was firm but mobile.
8

9 The gel was foamed using an aerosol canister and a fine
10 celled, thin foam was produced that stabilised
11 overnight into a sponge with good handling strength.
12

13 Example 9

14 A composition according to the present invention was
15 formed by admixing the following ingredients together:
16

17 3% Keltone
18 1% Cetrimide
19 80:20 di-ionised water : glycerol
20

21 A gel composition was formed and autoclaved at
22 approximately 121°C for 15 to 20 minutes. The gel
23 produced was firm but mobile.
24

25 Just before foaming 6g Arglaes powder (ie powdered
26 metal ion releasing glass) was added and the gel was
27 immediately foamed using an aerosol canister. A fine
28 celled, white foam was produced that eventually
29 stabilised into a firm sponge pad.
30

31 Example 10

32
33 A composition according to the present invention was
34 formed by admixing the following ingredients together:
35

36 3% Keltone

1 1% Cetrimide
2 80:20 di-ionised water : glycerol
3 0.1g Chlorohexidine

4
5 A gel composition was formed and autoclaved at
6 approximately 121°C for 15 to 20 minutes. The gel
7 produced was firm but mobile.

8
9 The gel was foamed using an aerosol canister and a fine
10 celled, thick foam was produced that stabilised
11 overnight into a sponge pad.

12
13 Example 11

14 A composition according to the present invention was
15 formed by admixing the following ingredients together:

16
17 2½% Keltone
18 2½% Carboxymethylcellulose
19 1% Cetrimide
20 80:20 di-water : glycerol

21
22 The gel composition formed was autoclaved at
23 approximately 121°C for 15 to 20 minutes. The gel
24 produced was firm but mobile.

25
26 The gel was foamed using an aerosol canister and a fine
27 celled, highly conformable, foam was produced. There
28 was little slump or flow, the foam was fairly stable,
29 cool and soothing. Once left to dry the flat foam
30 sheet was a still moist, cool sponge.

31
32 Example 12

33
34 A composition according to the present invention was
35 formed by admixing the following ingredients together:

36

- 1 2% Keltone
- 2 2% Hydroxypropylcellulose
- 3 1% Cetrimide
- 4 80:20 di-water : glycerol
- 5
- 6 The gel composition formed was autoclaved at
- 7 approximately 121°C for 15 to 20 minutes. The gel
- 8 produced was thick but mobile.
- 9
- 10 The gel was foamed using an aerosol canister and a fine
- 11 celled foam was produced. There was little slump or
- 12 flow, the foam was fairly stable, cool and soothing.
- 13 Once left to dry the flat foam sheet was a still moist,
- 14 cool sponge.

1 **CLAIMS**

2

3 1. A formulation for application to a body surface as
4 a foam, said formulation comprising, in admixture
5 or separately, a physiologically acceptable
6 foamable carrier and an active ingredient.

7

8 2. A formulation as claimed in Claim 1 wherein said
9 active ingredient is packaged separately to said
10 foamable carrier prior to foaming.

11

12 3. A formulation as claimed in either one of Claims 1
13 and 2 wherein said foamable carrier is alginate,
14 carboxymethylcellulose, collagen, a
15 polysaccharide, agar, a polyethylene oxide, a
16 glycol methacrylate, gelatin, a gum, or salts or
17 derivatives of any of these, or mixtures thereof.

18

19 4. A formulation as claimed in Claim 3 wherein said
20 foamable carrier is alginate, carboxymethyl-
21 cellulose, the derivatives or salts thereof, or
22 mixtures thereof.

23

24 5. A formulation as claimed in any one of Claims 1 to
25 4, wherein said foamable carrier has a molecular
26 weight of from 10,000 to 200,000 kDa.

27

28 6. A formulation as claimed in any one of Claims 1 to
29 5, wherein said active ingredient is a silver ion
30 releasing glass composition, chlorhexidine,
31 povidone iodine or cetrимide.

32

33 7. A formulation as claimed in any one of Claims 1 to
34 6 further containing a foaming agent.

35

36 8. A formulation as claimed in Claim 7 wherein said

- 1 foaming agent is cetrimide, lecithin, a soap,
2 silicone, a surfactant or the like.
3
- 4 9. A formulation as claimed in any one of Claims 1 to
5 8 in foamed form, wherein said active ingredient
6 is evenly distributed throughout the foam.
7
- 8 10. A formulation as claimed in any one of Claims 1 to
9 9 in the form of a foam sheet.
10
- 11 11. An apparatus to produce a foam for application to
12 a body surface, from a formulation as claimed in
13 any one of Claims 1 to 9, said apparatus
14 comprising:
15
- 16 a. a closed container having
17
- 18 i) a reservoir containing said foamable
19 carrier;
20
- 21 ii) a reservoir containing said active
22 ingredient; and
23
- 24 b. foaming means to produce a foam from said
25 foamable carrier.
26
- 27 12. An apparatus as claimed in Claim 11 wherein said
28 foamable carrier and said active ingredient are
29 admixed together and contained within the same
30 reservoir.
31
- 32 13. An apparatus as claimed in Claim 11 wherein said
33 foamable carrier and said active ingredient are
34 contained in separate reservoirs, and wherein said
35 apparatus includes means to evenly disperse active
36 ingredient into the foam.

- 1 14. An apparatus as claimed in any one of Claims 11 to
2 13 wherein said foaming means is an aerosol
3 canister.
4
- 5 15. Use of a formulation as claimed in any one of
6 Claims 1 to 10 for medical or veterinary purposes.
7
- 8 16. Use of a formulation as claimed in any one of
9 Claims 1 to 10 as a delivery system for the
10 controlled release of said active ingredient.
11
- 12 17. Use of a foamed formulation as claimed in Claim 9
13 or a foam sheet as claimed in Claim 10 as a wound
14 dressing.
15
- 16 18. A method of treatment of the human or animal body,
17 said method comprising administering to said body
18 a foamed formulation as claimed in Claim 9 or a
19 foam sheet as claimed in Claim 10.
20
- 21 19. A method as claimed in Claim 18 wherein said
22 foamed formulation or said foam sheet delivers
23 said active ingredient to said body in a
24 controlled release manner.
25
- 26 20. A method as claimed in either one of Claims 18 and
27 19 for treating burns or scalds.
28
29
30

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 95/02830

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61K9/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE WPI Week 9247 Derwent Publications Ltd., London, GB; AN 92-384885 & JP,A,04 282 311 (KOIKE KAGAKU) see abstract	1,3,6-9, 15-20
Y	---	3,4,6,10
Y	GB,A,2 207 865 (BIOGAL GYOGYSZERGYAR) 15 February 1989 see claims 1,5,6 see examples 1,2 --- -/--	3,4

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
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- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 95/02830

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>DATABASE WPI- Week 9113 Derwent Publications Ltd., London, GB; AN 91-092231 & JP,A,03 038 504 (SHINGAWA NENRYO) see abstract -----</p>	6,10

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 95/02830

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		AU-B- 2038788	09-02-89
		BE-A- 1001932	17-04-90
		BG-A- 49522	16-12-91
		CH-A- 675833	15-11-90
		DE-A- 3826419	16-02-89
		FR-A- 2619011	10-02-89
		JP-A- 1117828	10-05-89
		NL-A- 8801930	01-03-89
		SE-A- 8802805	05-02-89
